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EXAMINER	

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	19

DATE MAILED:

EXAMINER INTERVIEW SUMMARY RECORD

All participants (applicant, applicant's representative, PTO personnel):

(1) Joseph Woitach (3) Stephen E. Reiter

(2) Deborah Crouch (4) Jay Lichter

Date of interview July 25, 2001

Type: ☐ Telephonic ☒ Personal (copy is given to ☐ applicant ☒ applicant's representative).

Exhibit shown or demonstration conducted: ☐ Yes ☒ No. If yes, brief description: _____

Agreement ☐ was reached with respect to some or all of the claims in question. ☒ was not reached.

Claims discussed: pending + proposed claims (Faxed copy attached)

Identification of prior art discussed: None.

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:

The 112 1st rejection was discussed with regards to breadth of promoter used in the construct/mouse. Details of the phenotype for the transgenic and knock-out mice which were made, in particular evidence in the Form of a declaration, may be submitted.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

☒ 1. It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph below has been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW (e.g., items 1-7 on the reverse side of this form). If a response to the last Office action has already been filed, then applicant is given one month from this interview date to provide a statement of the substance of the interview.

☐ 2. Since the examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action. Applicant is not relieved from providing a separate record of the substance of the interview unless box 1 above is also checked.

Deborah Crouch
Examiner's Signature

PTOL-413 (REV. 2-93)

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SALK 2270-2 pending independent claims

13. (New) A transgenic mouse whose genome contains a transgene comprising a gene encoding a human steroid and xenobiotic receptor (SXR) polypeptide operably linked to an inducible promoter/enhancer,

wherein said SXR polypeptide is a member of the steroid/thyroid hormone superfamily and forms a heterodimer with retinoid X receptor,

wherein said SXR polypeptide binds to a direct or inverted repeat response element based on the half site RGBNNM,

wherein:

R is selected from A or G;
B is selected from G, C, or T;
each N is independently selected from A, T, C, or G; and
M is selected from A or C;

with the proviso that at least 4 nucleotides of said -RGBNNM- sequence are identical with the nucleotides at corresponding positions of the sequence AGTTCA;

wherein said SXR polypeptide inducibly activates transcription in response to a wide variety of natural and synthetic steroid hormones, including at least compounds that induce catabolic enzymes, steroid receptor agonists and antagonists, and bioactive dietary compounds, and

wherein said transgenic mouse expresses said SXR polypeptide in at least one of the liver and intestine.

23. (New) A transgenic knock-out mouse whose genome comprises a homozygous disruption in an endogenous SXR polypeptide gene, wherein said homozygous disruption prevents function of an endogenous SXR polypeptide and results in said transgenic knockout

mouse exhibiting decreased response to steroids and xenobiotics as compared to a wild-type mouse.

24. (New) A transgenic mouse whose genome contains a transgene comprising a gene encoding a human steroid and xenobiotic receptor (SXR) polypeptide operably linked to a constitutively active promoter/enhancer,

wherein said SXR polypeptide is a member of the steroid/thyroid hormone superfamily and forms a heterodimer with retinoid X receptor,

wherein said SXR polypeptide binds to a direct or inverted repeat response element based on the half site RGBNNM,

wherein:

R is selected from A or G;
B is selected from G, C, or T;
each N is independently selected from A, T, C, or G; and
M is selected from A or C;

with the proviso that at least 4 nucleotides of said -RGBNNM- sequence are identical with the nucleotides at corresponding positions of the sequence AGTTCA;

wherein SXR polypeptide inducibly activates transcription in response to a wide variety of natural and synthetic steroid hormones, including at least compounds that induce catabolic enzymes, steroid receptor agonists and antagonists, and bioactive dietary compounds, and

wherein said transgenic mouse expresses said SXR polypeptide in at least one of the liver and intestine.

35. (New) A method for producing a transgenic mouse, said method comprising:

injecting a one-cell mouse zygote with a transgene comprising a gene encoding a human steroid and xenobiotic receptor (SXR) polypeptide operably linked to an inducible or a constitutively active promoter/enhancer,

wherein said SXR polypeptide is a member of the steroid/thyroid hormone superfamily and forms a heterodimer with retinoid X receptor,

wherein said SXR polypeptide binds to a direct or inverted repeat response element based on the half site RGBNNM,

wherein:

R is selected from A or G;
B is selected from G, C, or T;
each N is independently selected from A, T, C, or G; and
M is selected from A or C;

with the proviso that at least 4 nucleotides of said -RGBNNM- sequence are identical with the nucleotides at corresponding positions of the sequence AGTTCA, and inducibly or constitutively activates transcription in response to a wide variety of natural and synthetic steroid hormones, including at least compounds that induce catabolic enzymes, steroid receptor agonists and antagonists, and bioactive dietary compounds, and

wherein said polypeptide is detectably expressed in at least one of the liver and the intestine, and ,

obtaining from the zygote a transgenic mouse that expresses said SXR polypeptide in the liver.

SALK 2270-2 proposed amendment #1

Alb promoter/enhancer

It is proposed that all currently pending claims (including claims 13, 23, 24 and 35) be cancelled and new claims be added, starting with new independent claims as follows (ADDED LANGUAGE RELATIVE TO PRIOR CLAIMS IS UNDERLINED TO HIGHLIGHT HOW THESE CLAIMS DIFFER FROM THEIR PREDECESSORS):

39. (New) A transgenic mouse whose genome contains a transgene comprising a gene encoding a human steroid xenobiotic receptor (SXR) polypeptide, or functional fragment of said polypeptide, operably linked to an inducible tissue-specific promoter/enhancer,

wherein said human SXR polypeptide is inducibly expressed in said transgenic mouse in a tissue-specific manner,

wherein said human SXR polypeptide is a member of the steroid/thyroid hormone superfamily and forms a heterodimer with retinoid X receptor,

wherein said **[human SXR polypeptide]** heterodimer binds to a direct or inverted repeat response element comprising at least two half sites RGBNNM separated by a spacer of 0 up to 15 nucleotides,

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wherein:

R is selected from A or G;

B is selected from G, C, or T;

each N is independently selected from A, T, C, or G; and

M is selected from A or C;

with the proviso that at least 4 nucleotides of said RGBNNM sequence are identical with the nucleotides at corresponding positions of the sequence AGTTCA; and

wherein compounds selected from the group consisting of natural and synthetic steroid hormones including at least compounds that induce catabolic enzymes, steroid receptor agonists and antagonists, and bioactive dietary compounds, interact with said human SXR polypeptide directly or indirectly to activate transcription of a gene under the control of a cytochrome P450 response element therefore.

58. (New) A transgenic knock-out mouse whose genome comprises a homozygous disruption in an endogenous mouse SXR polypeptide gene, wherein said homozygous disruption comprises insertion, deletion or point mutation of said mouse SXR polypeptide, wherein said disruption results in a change in SXR modulated response in said transgenic knockout mouse as compared to a wild-type mouse.

59. (New) A method for producing a transgenic mouse, said method comprising:

injecting a one-cell mouse zygote with a transgene comprising a gene encoding a human steroid xenobiotic receptor (SXR) polypeptide, or functional fragment of said polypeptide, operably linked to an inducible or a constitutively active tissue-specific promoter/enhancer,

wherein said human SXR polypeptide is inducibly or constitutively expressed in said transgenic mouse in a tissue-specific manner,

wherein said human SXR polypeptide is a member of steroid/thyroid hormone superfamily and forms a heterodimer with retinoid X receptor,

wherein said heterodimer binds to a direct or inverted repeat response element comprising at least two half sites RGBNNM separated by a spacer of 0 up to 15 nucleotides,

wherein:

R is selected from A or G;

B is selected from G, C, or T;

each N is independently selected from A, T, C, or G; and

M is selected from A or C;

with the proviso that at least 4 nucleotides of said - RGBNNM - sequence are identical with nucleotides at corresponding positions of the sequence AGTTCA,

wherein compounds selected from the group consisting of natural and synthetic steroid hormones including at least compounds that induce catabolic enzymes, steroid receptor agonists and antagonists, and bioactive dietary compounds, interact with said human SXR polypeptide directly or indirectly to activate transcription of a gene under the control of a cytochrome P450 response element therefore, and

obtaining a transgenic mouse from said mouse zygote, wherein said transgene is incorporated into the genome of said transgenic mouse and wherein said transgenic mouse expresses said human SXR polypeptide.

65. (New) A transgenic mouse whose genome contains a transgene comprising a gene encoding a human steroid xenobiotic receptor (SXR) polypeptide, or functional fragments of said polypeptide, operably linked to a constitutively active tissue-specific promoter/enhancer,

wherein said human SXR polypeptide is constitutively expressed in said transgenic mouse in a tissue-specific manner,

wherein said human SXR polypeptide is a member of the steroid/thyroid hormone superfamily and forms a heterodimer with retinoid X receptor,

wherein said heterodimer binds to a direct or inverted repeat response element comprising at least two half sites RGBNNM separated by a spacer of 0 up to 15 nucleotides,

wherein:

R is selected from A or G;

B is selected from G, C, or T;

each N is independently selected from A, T, C, or G; and

M is selected from A or C;

with the proviso that at least 4 nucleotides of said RGBNNM sequence are identical with the nucleotides at corresponding positions of the sequence AGTTCA; and

wherein compounds selected from the group consisting of natural and synthetic steroid hormones including at least compounds that induce catabolic enzymes, steroid receptor agonists and antagonists, and bioactive dietary compounds, interact with said human SXR polypeptide directly or indirectly to activate transcription of a gene under the control of a cytochrome P450 response element therefore.

SALK 2270-2 proposed amendment #2

39. (New) A transgenic mouse whose genome contains a transgene comprising a purified polynucleotide selected from the group consisting of:

(a) SEQ ID NO:1 or SEQ ID NO:1 wherein T can also be U, and nucleic acid sequences complementary thereto; and

(b) fragments of (a) having at least 20 contiguous bases that hybridize under stringent conditions to the polynucleotide as SEQ ID NO:1;

wherein said transgene is operably linked to an inducible tissue-specific promoter/enhancer,

wherein said human SXR polypeptide is inducibly expressed in said transgenic mouse in a tissue-specific manner,

wherein said human SXR polypeptide is a member of the steroid/thyroid hormone superfamily and forms a heterodimer with retinoid X receptor,

wherein said heterodimer binds to a direct or inverted repeat response element comprising at least two half sites RGBNNM separated by a spacer of 0 up to 15 nucleotides,

wherein:

R is selected from A or G;

B is selected from G, C, or T;

each N is independently selected from A, T, C, or G; and

M is selected from A or C;

with the proviso that at least 4 nucleotides of said RGBNNM sequence are identical with the nucleotides at corresponding positions of the sequence AGTTCA; and

wherein compounds selected from the group consisting of natural and synthetic steroid hormones including at least compounds that induce catabolic enzymes, steroid receptor agonists

and antagonists, and bioactive dietary compounds, interact with said human SXR polypeptide directly or indirectly to activate transcription of a gene under the control of a cytochrome P450 response element therefore.

58. (New) A transgenic knock-out mouse whose genome comprises a homozygous disruption in a mouse SXR polypeptide gene, wherein said homozygous disruption comprises insertion, deletion or point mutation of said mouse SXR polypeptide, wherein said disruption results in a change in SXR modulated response in said transgenic knockout mouse as compared to a wild-type mouse. decrease?

59. (New) A method for producing a transgenic mouse, said method comprising:

injecting a one-cell mouse zygote with a transgene comprising a purified polynucleotide selected from the group consisting of:

(a) SEQ ID NO:1 or SEQ ID NO:1 wherein T can also be U, and nucleic acid sequences complementary thereto; and

(b) fragments of (a) having at least 20 contiguous bases that hybridize under stringent conditions to the polynucleotide as SEQ ID NO:1;

wherein said transgene is operably linked to an inducible or a constitutively active tissue-specific promoter/enhancer,

wherein said human SXR polypeptide is inducibly or constitutively expressed in said transgenic mouse in a tissue-specific manner,

wherein said human SXR polypeptide is a member of steroid/thyroid hormone superfamily and forms a heterodimer with retinoid X receptor,

wherein said heterodimer binds to a direct or inverted repeat response element comprising at least two half sites RGBNNM separated by a spacer of 0 up to 15 nucleotides,

wherein:

R is selected from A or G;

B is selected from G, C, or T;

each N is independently selected from A, T, C, or G; and

M is selected from A or C;

with the proviso that at least 4 nucleotides of said - RGBNNM - sequence are identical with nucleotides at corresponding positions of the sequence AGTTCA,

wherein compounds selected from the group consisting of natural and synthetic steroid hormones including at least compounds that induce catabolic enzymes, steroid receptor agonists and antagonists, and bioactive dietary compounds, interact with said human SXR polypeptide directly or indirectly to activate transcription of a gene under the control of a cytochrome P450 response element therefore, and

obtaining a transgenic mouse from said mouse zygote, wherein said transgene is incorporated into the genome of said transgenic mouse and wherein said transgenic mouse expresses said human SXR polypeptide.

65. (New) A transgenic mouse whose genome contains a transgene comprising a purified polynucleotide selected from the group consisting of

(a) SEQ ID NO:1 or SEQ ID NO:1 wherein T can also be U, and nucleic acid sequences complementary thereto; and

(b) fragments of (a) having at least 20 contiguous bases that hybridize under stringent conditions to the polynucleotide as SEQ ID NO:1;

wherein said transgene is operably linked to a constitutively active tissue-specific promoter/enhancer,

wherein said human SXR polypeptide is constitutively expressed in said transgenic mouse in a tissue-specific manner,

wherein said human SXR polypeptide is a member of the steroid/thyroid hormone superfamily and forms a heterodimer with retinoid X receptor,

wherein said heterodimer binds to a direct or inverted repeat response element comprising at least two half sites RGBNNM separated by a spacer of 0 up to 15 nucleotides,

wherein:

R is selected from A or G;

B is selected from G, C, or T;

each N is independently selected from A, T, C, or G; and

M is selected from A or C;

with the proviso that at least 4 nucleotides of said RGBNNM sequence are identical with the nucleotides at corresponding positions of the sequence AGTTCA; and

wherein compounds selected from the group consisting of natural and synthetic steroid hormones including at least compounds that induce catabolic enzymes, steroid receptor agonists and antagonists, and bioactive dietary compounds, interact with said human SXR polypeptide directly or indirectly to activate transcription of a gene under the control of a cytochrome P450 response element therefore.

SALK 2270-2 proposed amendment #3

39. (New) A transgenic mouse whose genome contains a transgene comprising a purified polynucleotide having the nucleotide sequence set forth in SEQ ID NO:1, a complementary sequence thereto, or fragments having at least 20 contiguous bases that hybridize under stringent conditions to SEQ ID NO: 1, operably linked to an inducible tissue-specific promoter/enhancer,

wherein said human SXR polypeptide is inducibly expressed in said transgenic mouse in a tissue-specific manner,

wherein said human SXR polypeptide is a member of the steroid/thyroid hormone superfamily and forms a heterodimer with retinoid X receptor,

wherein said heterodimer binds to a direct or inverted repeat response element comprising at least two half sites RGBNNM separated by a spacer of 0 up to 15 nucleotides,

wherein:

R is selected from A or G;

B is selected from G, C, or T;

each N is independently selected from A, T, C, or G; and

M is selected from A or C;

with the proviso that at least 4 nucleotides of said RGBNNM sequence are identical with the nucleotides at corresponding positions of the sequence AGTTCA; and

wherein compounds selected from the group consisting of natural and synthetic steroid hormones including at least compounds that induce catabolic enzymes, steroid receptor agonists and antagonists, and bioactive dietary compounds, interact with said human SXR polypeptide directly or indirectly to activate transcription of a gene under the control of a cytochrome P450 response element therefore.

58. (New) A transgenic knock-out mouse whose genome comprises a homozygous disruption in a mouse SXR polypeptide gene, wherein said homozygous disruption comprises insertion, deletion or point mutation of said mouse SXR polypeptide, wherein said disruption results in a change in SXR modulated response in said transgenic knockout mouse as compared to a wild-type mouse.

59. (New) A method for producing a transgenic mouse, said method comprising:

injecting a one-cell mouse zygote with a transgene comprising a purified polynucleotide having the nucleotide sequence set forth in SEQ ID NO:1, a complementary sequence thereto, or fragments having at least 20 contiguous bases that hybridize under stringent conditions to SEQ ID NO: 1, operably linked to an inducible or a constitutively active tissue-specific promoter/enhancer,

wherein said human SXR polypeptide is inducibly or constitutively expressed in said transgenic mouse in a tissue-specific manner,

wherein said human SXR polypeptide is a member of steroid/thyroid hormone superfamily and forms a heterodimer with retinoid X receptor,

wherein said heterodimer binds to a direct or inverted repeat response element comprising at least two half sites RGBNNM separated by a spacer of 0 up to 15 nucleotides,

wherein:

R is selected from A or G;

B is selected from G, C, or T;

each N is independently selected from A, T, C, or G; and

M is selected from A or C;

with the proviso that at least 4 nucleotides of said - RGBNNM - sequence are identical with nucleotides at corresponding positions of the sequence AGTTCA,

wherein compounds selected from the group consisting of natural and synthetic steroid hormones including at least compounds that induce catabolic enzymes, steroid

human SXR polypeptide directly or indirectly to activate transcription of a gene under the control of a cytochrome P450 response element therefore.

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